Remarks

By the present Amendment, claims 119 and 123 have been cancelled, and claims 120-122 and 124-126 amended. Claims 128 and 129are newly presented for consideration. Various amendments have also been made to the specification. Accordingly, claims 120-122, 124-126, 128, and 129 are now pending in the application.

In the Office Action of April 20, 2004, claims 119-126 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 119-126 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The cancellation of claims 119 and 123 renders some of these grounds of rejection moot. With respect to the remaining claims, these rejections are respectfully traversed.

I. Support for Claim Amendments

Claims 128 and 129 have been added to more clearly define the invention by addressing, at least in part, some of the issues raised in the Office Action. Claims 120-122 and 124-126 have also been amended to address issues of indefiniteness raised in the Office Action. Applicants respectfully submit that the amended claims are fully supported by the specification. Accordingly, no new matter is added by this Amendment and entry thereof is respectfully requested.

II. Sequence Rule Non-Compliance

The specification has been amended to include the corresponding sequence identification numbers cited along with each sequence in the specification on page 45, line 12. Moreover, the paragraph beginning at page 46, line 11 ([0155]) and Table 10 have been amended to include the sequence and corresponding sequence identification numbers, as suggested by the Examiner. Accordingly, no new matter is added by this Amendment and entry thereof is respectfully requested. Applicants respectfully point out that sequences fewer than four specifically defined nucleotides or amino acids are excluded from this requirement under 37 C.F.R. § 1.821(a).

Accordingly, the sequences at page 45, paragraphs 2 and 3 ([0151] and [0152]) were not included in the sequence listing. Substitute sheets of the "Sequence Listing" and a substitute copy of the computer readable form including all previously submitted data SEQ ID NOS: 48 and 49 are submitted together with the present Amendment. Applicants respectfully submit that the substitute sheets include no new matter and are fully supported by the original specification. The copy in computer readable form is the same as the substitute copy of the "Sequence Listing" and includes no new matter.

III. Rejection under 35 U.S.C. § 101

Claims 119-126 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. The Examiner states that the instant claims do not require performance of a result outside of a computer. The Examiner further states that claim 119 cites an apparatus but is reasonably deemed a computer as its general embodiment that performs determination and identification without any requirements of physical action or movement cited in the claims. In addition, the Examiner states that claims 123-126 cite a computer program product which is "tangible embodying a program..." but without citing any tangible physical transformation in the actual steps of the program.

Applicants respectfully disagree with these assertions. The claimed invention does more than mere manipulation of data, and the results achieved are both beneficial and tangible. Additionally, Applicants do not believe that the rejection is properly sustained.

According to the M.P.E.P., "the claimed invention as a whole must accomplish a practical application." (*Emphasis added*). Accordingly, examination requires a determination of (i) what the invention is, and (ii) how the claims relate to and define the invention. The burden is on the Patent Office to establish a *prima facie* case that the invention is directed to an abstract idea, or fails to produce any useful results. The Office Action must expressly state how the language of the claims is being interpreted to support the rejection. According to §2106:

> The applicant is in the best position to explain why an invention is believed useful. Office personnel should therefore focus their efforts on pointing out

> statements made in the specification that identify all practical applications for the invention. Office personnel should rely on such statements throughout the examination when assessing the invention for compliance with all statutory criteria.

The M.P.E.P. also provides examples (in the form of citations to caselaw) of patentable inventions. Several such examples are listed below:

> Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held to be directed to patentable subject matter because "the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle." AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 1358, 50 USPQ2d 1447, 1452 (Fed.Cir. 1999);
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> "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces ' a useful, concrete and tangible result ' --a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." State Street, 149 F.3d at 1373, 47 USPQ2d at 1601;
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> A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.
>
> A method of using a computer processor to receive data representing Computerized Axial Tomography ("CAT") scan images of a patient, performing a calculation to determine the difference between a local value at a data point and an average value of the data in a region surrounding the point, and displaying the difference as a gray scale for each point in the image, and displaying the resulting image. In this example the data is an intangible representation of a physical object, i.e., portions of the anatomy of a patient. The transformation occurs when the condition of the human body is measured with X-rays and the X-rays are converted into electrical digital signals that represent the condition of the human

body. The real world value of the invention lies in creating a new CAT scan image of body tissue without the presence of bones.

Independent claim 128 defines an apparatus for identifying a culture medium component that comprises, in part:

> ...
>
> means for determining a relationship between a measured indicia of a property of said plurality of first culture media and at least one parameter of said first test compounds; and
>
> means for identifying a second test library containing a plurality of second culture media based on said determined relationship;
>
> said plurality of second culture media containing a plurality of second test compounds having an estimated indicia which meets a test requirement relating to the measured indicia.

The invention defined by independent claim 128 determines a relationship between a measured indicia of the first culture media and at least one parameter of the first test compounds. The indicia can reflect, under certain circumstances, a value of the property of the first culture media. Next, means are provided for identifying a second test library containing a plurality of second culture media. The second test library is selected based on the previously determined relationship. According to one or more embodiments of the invention, the relationship can have a mathematical component capable of being applied to other culture media. Additionally, the second test compounds have an estimated indicia which is determined using the relationship. The second culture media are selected such that their estimated indicia meet a test requirement. The test requirement can be set by a user (i.e., researcher) based on desired properties, characteristics, or research being performed.

As can be appreciated, one or more embodiments of the invention provide a second test library that contains actual lead compounds expected to have certain properties that the user seeks. The lead compounds can subsequently be tested to confirm the presence of these desired properties. This can be particularly useful, for example, in situations where a high number of compounds exist (e.g., peptide identification). It can often be expensive and time consuming to

test individual compounds to identify those having desired properties using conventional methods. Thus, the actual number of experiments conducted can be reduced.

The claimed invention can be used, in part, to reduce time and costs by predicting a subset of compounds (from a very large library of compounds) that will have the desired properties. A user would then take the compounds identified in the second test library and conduct actual experimentation to obtain more accurate values for the desired properties. For example, the second test library identified using the apparatus of claim 128 can be used to assist a researcher in the identification of a culture medium component that possesses a desired characteristic. The apparatus uses qualitative and/or quantitative data from the test compounds to predict candidate compounds having a particular activity as determined by the user. This can significantly reduce the number of experiments, and costs, associated with identifying desired compounds.

Applicants respectfully submit that (1) the claimed invention provides a tangible result in the form of second test compounds, and (2) one skilled in the art would readily appreciate that this invention has specific, substantial, and a real world utility in terms of cost and time reductions associated with the amount of experimentation necessary to identify useful compounds in research settings.

Newly presented claim 129 defines a computer program product having limitations which correspond closely to those of independent claim 128. Accordingly, it is also believed that independent claim 129 provides a tangible result and has real world utility.

It is therefore respectfully submitted that claims 120-122, 124-126, 128, and 129 fully satisfy the requirements of 35 U.S.C. §101.

IV. Rejection under 35 U.S.C. § 112, second paragraph

Claims 119-126 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In support of this rejection, the Examiner principally identifies that, in claim 119,

a relationship is determined but without connection or definition of cooperativity between measured first indicia in order to define either the "relationship" in claim 119 or the connection of such a "relationship" to the "$\hat{y}_i$" values, recited in claim 120. The Examiner additionally asserts that similar vagueness and indefiniteness are present in claims 123 as compared to claim 124. The Examiner further states that connection between distance determinations of claims 122 or 126 to the relationship or "$\hat{y}_i$" are also undefined and vague.

Applicants have reviewed and made amendments to the claims that should remedy all instances of indefiniteness. For example, claims 119 and 123 have been cancelled and respectively replaced with claims 128 and 129. Claims 120 and 124 have been amended to clarify that the relationship is in the form of $\underline{\hat{y}_i=f(x_{ij})}$. As set forth in claims 128 and 129, there is a plurality of first culture media. Accordingly, in dependent claims 120 and 124, the subscript "i" reflects the total number of culture media, which ranges from 1-n. The subscript "j" represents the number of parameters (from the "at least one parameter" recited in claims 128 and 129), and ranges from 1-d. $\underline{X_{ij}}$ represents the multiple parameters. Thus, $\underline{\hat{y}_i}$ provides a relationship between the number of culture media and the parameters of the test compounds. This relationship can then be used to predict (or estimate) the indicia of other culture media (i.e., the second culture media) without actually conducting experiments to measure the values.

With respect to claims 122 and 126, the Office Action indicates that the language is vague and indefinite because the connection between the distance determination and the relationship (or $\underline{\hat{y}_i}$ values) was undefined.

Applicants respectfully disagree with this assertion as well. Claims 122 and 126 define the relationship recited in claims 128 and 129 in terms of a distance function. As recited in independent claims 128 and 129, each first culture medium contains a respective first test compound. The first test compound further has at least one parameter. The distance function calculates a value (or distance) between a parameter of the first test compound and a value of a corresponding parameter of a second (untested) test compound. Furthermore, the second test compound is selected such that it is not within the plurality of first test compounds. A cutoff

distance is defined by the user so that a property of culture medium containing the second test compound can be estimated if the distance function is less than the cutoff distance. As set forth in the specification, the distance function provides an estimated indicia of the property that corresponds to the measured indicia determined from a culture medium containing a first tested compound from the first test library. Once a lead compound is identified from the first test library, additional lead compounds can be determined based on an assumption that compounds that are close in parameter space will exhibit similar or better activities. See page 34, lines 1-23 of the disclosure.

It is therefore respectfully submitted that all of the pending claims satisfy the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is respectfully requested.

V. Informalities

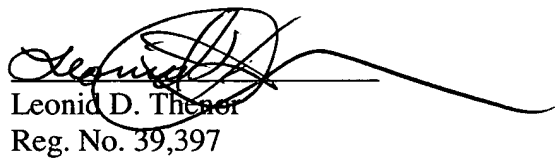
The Examiner objected to claims 120-122 and 124-126 by stating that the parameters wherein subscripts are present are printed with too small of a font to read them clearly. Applicant has amended claims 120-122 and 124-126 to correct the noted informality. Withdrawal of this rejection is respectfully requested.

Authorization

The Commissioner is hereby authorized to charge any additional fees that may be required for this Response, or credit any overpayment, to deposit account number 08-0219.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of which is required to make this response timely, and is hereby authorized to charge any fee for such, to deposit account number 08-0219.

Respectfully submitted,



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